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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,066	01/29/2002	Norman Barton M.D	10793/52	2582
23838	7590	08/29/2006	EXAMINER	
KENYON & KENYON LLP 1500 K STREET N.W. SUITE 700 WASHINGTON, DC 20005			CHONG, YONG SOO	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/058,066	Applicant(s) M.D ET AL.	
	Examiner Yong S. Chong	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/21/2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74-129 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74-129 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/21/2006 has been entered.

Claim(s) 1-73 has been cancelled. Claim(s) 113-129 have been added. Claim(s) 74-129 are pending. Claim(s) 74, 76, 78-81, 88, 90, 99-112 been amended. Claim(s) 74-129 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The 103(a) rejection is maintained for reasons of record and now reflects the new amendments to the claims below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 74-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fishbein (US Patent 6,576,659).

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Fishbein teaches the treatment of wounds, in general, with an effective amount of oxandrolone. In particular, the patient is experiencing involuntary weight loss as a result of the wound (abstract; col. 3, lines 20-23). Examples of wounds are punctures, incisions, excisions, lacerations, abrasions, ulcers and burns (col. 3, lines 51-56). Oral (systemic) and topical administrations are taught (col. 3, line 60 to col. 4, line 14). The preferred effective amount as disclosed by Fishbein et al. is about 1-100 mg per day (col. 4, lines 29-30), encompassing the preferred amounts herein as stated in the specification (pg. 14, lines 1-3).

Fishbein does not specifically teach the preferred dosage nor does Fishbein teach of the specific instances of wound treatment as claimed herein.

It would have been obvious to one of ordinary skill in the art at the time of the invention to treat the wounds as instantly claimed because Fishbein teaches the treatment of wounds in general. Accordingly, absent a showing of unexpected results, the skilled artisan would have been motivated to treat each of the individual instances of wounds, as herein claimed, because of an expectation of success in treating the various species of wounds encompassed by the genus of wounds taught by Fishbein.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time of the invention to treat wounds utilizing the claimed dosages because Fishbein teaches the treatment of wounds utilizing oxandrolone in general and it is well established that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

Applicant argues that the pending claims do not relate to a method of treatment comprising administration of oxandrolone per se, as taught by Fishbein et al., but instead relate to the administration of an anabolic steroid exhibiting the specified functional characteristics, such as expression of type I and/or type III procollagen by human fibroblasts.

Examiner respectfully points out that the invention disclosed by Fishbein et al. does indeed read on the claimed anabolic steroid. Moreover, the limitations regarding the expression of type I and/or type III procollagen by human fibroblasts is an inherent property of oxandrolone administration.

It is well known in Patent Law that if applicants are claiming a biological pathway as the basis for their invention then a mechanism by which the active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects which would result from the claimed method. The patient, condition to be treated, and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims. Furthermore, applicant's arguments herein are related to the mechanism of action of an agent in the treatment. Note that the mechanism of action of an agent in the treatment, by itself, does not have a bearing on the patentability of the invention if the method steps are already known even though applicant has proposed or claimed the mechanism. Applicant's recitation

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of a new mechanism of action for the prior art method *will not, by itself, distinguish* the instant claims over the prior art teaching the same or nearly the same method steps.

“Products of identical chemical composition can not have mutual exclusive properties.” Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC

S. SHENGJUN WANG
PRIMARY EXAMINER